UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Jason Juliar,

Plaintiff,

v.

MEMORANDUN OPINION AND ORDER
No. 21-cv-354 (MJD/BRT)

Ethicon, Inc. and
Johnson and Johnson,

Defendants.

Adam M. Evans, Brenes Law Group, P.C. and Yvonne M. Flaherty, Lockridge Grindal Nauen PLLP, Counsel for Plaintiff.

Tracy J. Van Steenburgh and Brandie Morgenroth, Nilan Johnson Lewis PA and Richard M. Dye, Butler Snow LLP, Counsel for Defendants.

This matter is before the Court on Defendants' Motion to Dismiss the First Amended Complaint ("FAC"). [Doc. No. 48]

I. Factual Background

Defendants Ethicon, Inc. and Johnson and Johnson developed, tested, designed, manufactured, inspected, marketed, labeled, promoted, distributed and sold the Ethicon Proceed Mesh for use in repairing hernias. (FAC ¶ 2.)

On September 14, 2016, Plaintiff was implanted with a Proceed Mesh to repair a ventral hernia. (FAC ¶ 66.) On February 7, 2017, Plaintiff underwent a mesh revision procedure, and during this procedure, Plaintiff's physician observed that the Proceed Mesh had ruptured in the center, causing re-herniation and strangulation, resulting in necrosis of the small bowel. (FAC ¶ 67.) Plaintiff's physician had to perform an emergency bowel resection and re-anastomosis, resection of the Proceed Mesh and application of a wound VAC. (Id.)

Plaintiff claims the Proceed Mesh is unreasonably dangerous due to its defective design and that Defendants knew of the defects but concealed such knowledge from Plaintiff's physician, the hospital and the FDA, and that Plaintiff suffered as a result. (FAC ¶¶ 3-5.)

Plaintiff brought this action on February 5, 2021, and asserts the following claims against Defendants: Count I, Negligence; Count II, Strict Liability – Manufacturing Defect; Count III, Strict Liability – Failure to Warn; Count IV, Breach of Express Warranty; Count V, Breach of Implied Warranty of Merchantability and Fitness of Purpose; Count VI, Strict Liability – Design Defect; and Count VII, New Jersey Consumer Fraud Act.

II. Standard for Motion to Dismiss

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a party may move the Court to dismiss a claim if, on the pleadings, a party has failed to state a claim upon which relief may be granted. In reviewing a motion to dismiss, the Court takes all facts alleged in the complaint to be true. Zutz v. Nelson, 601 F.3d 842, 848 (8th Cir. 2010).

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. Thus, although a complaint need not include detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.

Id. (citations omitted).

In deciding a motion to dismiss, the Court considers the complaint and "materials that are part of the public record or do not contradict the complaint, as well as materials that are necessarily embraced by the pleadings. For example, courts may consider matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint." Greenman v. Jessen, 787 F.3d 882, 887 (8th Cir. 2015) (citations omitted).

III. Discussion

Plaintiff has asserted separate strict liability and negligence claims based on manufacturing defect, design defect and failure to warn. Under Minnesota law, claims of negligence and strict liability are merged into a single products liability theory. Green Plains Otter Tail, LLC v. Pro-Environmental, Inc., 953 F.3d 541, 546 (8th Cir. 2020) (quoting Thompson v. Hirano Tecseed Co., Ltd., 456 F.3d 805, 808 (8th Cir. 2006) (applying Minnesota law)). The Court will thus analyze each of the design defect, manufacturing defect and failure to warn claims as one claim rather than as separate negligence and strict liability claims. See Dolan v. Boston Scientific Corp., No. 20-cv-1827 (NEB/LIB), 2021 WL 698777 at *1 (D. Minn. Feb. 23, 2021).

A. Manufacturing Defect Claim

To prevail on a manufacturing defect claim, Plaintiff must prove there is a manufacturing flaw that renders a product unreasonably dangerous. Perry v. Boston Scientific Family, 16-cv-137 (PJS/HB), 2016 WL 10637082, at *5 (D. Minn. Dec. 1, 2016). "[T]he core of a manufacturing-defect case is some manufacturing flaw—some deviation from a flawless product—that renders a product

unreasonably dangerous." Id. (quoting Kapps v. Biosense Webster, Inc., 813 F. Supp. 2d 1128, 1147 (D. Minn. 2011) (applying Minnesota law)).

Here, Plaintiff has not alleged any facts to support a claim that the Proceed Mesh implanted in him was defectively manufactured. The only allegation relevant to the manufacturing defect claim provides: "The Proceed Mesh contained a manufacturing defect when it left the possession of Defendants. The Proceed Mesh differed from said Defendants' intended result and/or from other ostensibly identical units of the same product line." (FAC ¶ 112.) Plaintiff does not identify the specific manufacturing defect or how it differed from Defendants' intended result. Plaintiff also fails to allege facts that would show his claimed injuries are attributable to any such manufacturing defect, instead only asserting a conclusory allegation. (See id. ¶ 114 ("As a result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries and has endured substantial pain and suffering.").)

Because Plaintiff has failed to provide sufficient factual allegations that the product at issue contained a manufacturing defect, dismissal of the manufacturing defect claim is warranted. See Russell v. Ethicon, Inc., Civil Action No. GLR-20-1968, 2021 WL 1530086, at *2 (D. Md. Apr. 19, 2021)

(dismissing manufacturing defect claim as plaintiff did not identify any specific defect in the manufacturing process of her implant that proximately caused her injuries, and failed to allege how the implant departed from the intended design specifications for the device.); Meredith v. Medtronic, No. 3:18-cv-127-RGE-HCA, 2019 WL 6330677, at *5 (S.D. Iowa Oct. 25, 2019) (same); Cofresi v. Medtronic, Inc., 450 F. Supp.3d 759, 767 (S.D. Tex. 2020) (finding plaintiff did not allege a particular mishap occurred in the manufacturing process that rendered the product unreasonably dangerous or somehow the product deviated from the specifications or planned output in a manner that renders it unreasonably dangerous).

B. Failure to Warn

Under Minnesota law, a failure to warn claim has the following elements: "(1) the defendant[ ] had reason to know of the dangers of using the product; (2) the warnings fell short of those reasonably required, breaching the duty of care; and (3) the lack of an adequate warning caused the plaintiff's injuries." In re Levaquin Prods. Liab. Litig., 700 F.3d 1161, 1166 (8th Cir. 2012) (internal quotations omitted). In addition, Minnesota has adopted the learned intermediary doctrine. Id.

> Under the learned-intermediary doctrine, a maker of drugs or medical devices has a duty to warn only doctors (the learned intermediaries)—and not patients—about the dangers associated with a drug or medical device. Thus, the learned-intermediary doctrine forecloses a patient's failure-to-warn claim if a drug company or medical-device manufacturer provides an adequate warning to the patient's doctor. Further, the learned-intermediary doctrine forecloses a patient's failure-to-warn claim if a doctor (1) was aware of the information that, according to the plaintiff-patient, a defendant drug company or medical-device manufacturer wrongly failed to provide, and (2) would have taken the same action even if the defendant had included that information in a warning.

Kapps v. Biosense Webster, Inc., 813 F.Supp.2d 1128, 1152 (D. Minn. 2011).

Plaintiff alleges that the Proceed Mesh Instructions for Use ("IFU") failed to adequately warn of the risk of certain complications, such as "inflammatory response and rate of infection, adhesion formation, chronic pain, seroma formation, fistula formation, hematomas, mesh contracture and hernia recurrence." (FAC ¶ 53.) The issue, however, is whether the IFU failed to warn of a condition that Plaintiff experienced and that was not known by his surgeon or commonly known to other hernia surgeons. Defendants argue that the FAC does not adequately plead how the Proceed Mesh warnings were inadequate because it does not show how the warnings should have been different or how Plaintiff's injuries were proximately caused by any alleged deficiencies in the warnings. Plaintiff also fails to allege how Plaintiff's surgeon acted in reliance on

the deficiencies in the warnings or how he would have acted differently if different warnings had been provided[1].

Defendants argue that other courts have found that similarly threadbare allegations were insufficient to survive a Rule 12(b)(6) motion. See e.g. Dolan, 2021 WL 698777, at *3 (dismissing failure to warn claim because plaintiff did not allege that a hypothetical warning would have changed the course of events – that prescribing physician would not have used product if properly apprised of the risks).

Plaintiff responds the FAC includes allegations concerning the specific complications he suffered – mesh rupture (FAC ¶ 67), Defendants' knowledge of the heightened risk for that complication (FAC ¶¶ 76, 105), the absence of said complications from the IFU and other warning materials (FAC ¶¶ 61, 119), and that neither Plaintiff nor his physician would have agreed to use the defective product had the risks of mesh rupture been disclosed to them (FAC ¶ 120).

[1] Defendants also argue that Plaintiff did not attach the IFU or set forth the full context of the warnings provided by Defendants in the FAC. Without the details of the warnings provided, Plaintiff cannot show whether he suffered from a complication that was not included in the warnings and that his surgeon was unaware of the risk of the implantation of the device. The Court cannot rule on this argument without first reviewing the IFU. As that document is not part of the record, this argument is best left for summary judgment.

The Court finds these allegations sufficient allege a failure to warn claim, therefore the motion to dismiss the failure to warn claim is denied.

C. Design Defect Claim

The elements of a design defect claim are: 1) a product was in a defective condition unreasonably dangerous for its intended use; 2) the defect existed when it left the manufacturer's control; and 3) the defect was the proximate cause of the injury sustained. Drager by Gutzman v. Aluminum Indus. Corp., 495 N.W.2d 879, 882 (Minn. Ct. App. 1993). Minnesota courts apply a reasonable care balancing test to determine whether a product is defective:

> [A] manufacturer is obligated to exercise that degree of care in his plan or design so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the danger when the product is used in the manner for which the product was intended, as well as an unintended yet reasonably foreseeable use.

Id.

Defendants argue that the FAC includes only conclusory allegations in support of the design defect claim; Plaintiff does not identify what the design defect is, and he fails to plead any facts to link his injuries to the defect. See Dolan, 2021 WL 698777, at *2 (finding plaintiff failed to state a claim for design defect where the complaint lacked factual allegations specific to plaintiff and her

injuries, which design defect caused her injury, whether plaintiff was pain free before the implantation of the sling, what outcome plaintiff anticipated or what other factors may have contributed to plaintiff's injuries); see also Green v. Covidien, LP, 18-cv-2939, 2021 WL 1198833, at *5 (S.D.N.Y. Mar. 30, 2021) (finding that generic statement of causation did not explain how the product's defective design proximately caused plaintiff's injuries and did not explain why the product is more likely the cause of plaintiff's injuries).

The Court finds that the FAC sufficiently alleges a design defect claim. The FAC includes the allegation that the gamma irradiation – the method which Defendants chose to both sterilize the Proceed Mesh and convert the cellulose layer into a dissolvable compound – reduces the tensile strength of the Proceed Mesh and creates the unreasonably dangerous condition of being embrittled and weak. (FAC ¶¶ 37-42.) The FAC further alleges that this aspect of the design existed at the time the product left Defendants' control (FAC ¶ 153), made the product unreasonably dangerous by virtue of its unreasonably high rate of rupture (FAC ¶¶ 40-41), that Plaintiff underwent a mesh revision in February 2017 because the Proceed Mesh previously implanted had ruptured, causing re-

herniation and strangulation and resulting necrosis (FAC ¶ 67), and that such design defect caused Plaintiff's injuries (FAC ¶¶ 105, 157).

D. Negligence Claim

The elements of a negligence claim are: 1) the existence of a duty; 2) a breach of that duty; 3) an injury; and 4) the breach of duty was a proximate cause of the injury. McDougall v. CRC Indus., No. 20-1499 (JRT/LIB), __ F. Supp. 3d __, 2021 WL 810635 (D. Minn. Mar. 3, 2021) (citing Domagala v. Rolland, 805 N.W.2d 14, 22 (Minn. 2011)). In a products liability case, Minnesota law traditionally only recognizes three causes of action: design defect, manufacturing defect and failure to warn. Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517, 1527 (D. Minn. 1989) (citing Bilotta v. Kelley Co. , 346 N.W.2d 616, 622 (Minn. 1984)). Defendants argue that to the extent that Plaintiff seeks to assert his negligence claim under a different theory, such as negligent testing, such theory is not recognized under Minnesota law as an independent cause of action and is not supported by sufficient factual allegations. See J.D.O. ex rel. Oldenburg v. Gymboree Corp., No. 12-cv-71 (SRN/JSM), 2013 WL 6196970, at *9 (D. Minn. Nov. 27, 2013) ("Negligent failure to test is not an independent cause of action under Minnesota law. Rather, the duty to test is a 'subpart of duties to design a

product non-negligently, manufacture a product non-negligently, and provide adequate warnings of dangers associated with its use.'")

Plaintiff argues the Bilotta case does not stand for the proposition that strict liability and negligence claims are co-extensive. Instead, Bilotta noted that the unified theory of recovery was available with regard to claims of defective design and failure to warn, but the court did not extend its holding to negligence-based claims arising from other breaches of a manufacturer's duties. See Kapps, 813 F. Supp. 2d at 1147 (finding that "Bilotta leaves open the theoretical possibility of a distinction between theories of negligence and strict liability in a manufacturing-defect case. . . . If a dangerous manufacturing flaw existed and resulted from negligence, a plaintiff could, in theory recover in negligence; if a dangerous flaw existed but did not result from negligence, a plaintiff could recover in strict liability.")

Plaintiff cites no authority, however, to support a claim of negligence based on a theory of failure to test, analyze or distribute. See J.D.O. ex rel. Oldenburg, 2013 WL 6196970, at *9 (finding that Minnesota does not recognize a negligent failure to test claims). Rather, these theories are merely components of a design defect or a failure to warn claim.

Thus, while testing or failure to test may be introduced to support a claim of negligent failure to warn or design defect, Plaintiff cannot assert an independent action of negligent failure to test. See JDO ex rel. Oldenburg, 2013 WL 6196970 at *9. The same is true regarding Plaintiff's allegations that Defendant: 1) failed to implement feasible safety improvements; 2) failed to properly analyze the data resulting from any pre-market testing; 3) failed to conduct sufficient post-market testing and surveillance of the Proceed Mesh; 4) failed to disseminate proper instructions to avoid foreseeable harm that could result from using the Proceed Mesh; 5) failed to exercise due care when advertising and promoting the Proceed Mesh; and 6) negligently continued to manufacture, market, advertise and distribute the Proceed Mesh after Defendants knew or should have known of its adverse effects.

E. Breach of Warranty Claims

Defendants argue that Counts IV and V are time-barred, therefore they are subject to dismissal. Under Minnesota's Uniform Commercial Code, a breach of warranty claim must be brought within four years of "when tender of delivery is made." Minn. Stat. § 336.2-725(2). Here, "tender of delivery" of the Proceed Mesh would have occurred no later than September 14, 2016, when Plaintiff

alleges he was implanted with the Proceed mesh. This action was filed approximately four and one-half years later, on February 5, 2021.

Defendants further note that under Minnesota law, where a tender of delivery has been accepted, a plaintiff asserting a claim for breach of warranty, express or implied, must within a reasonable time after he discovers or should have discovered the breach, notify the seller of the breach or be barred from any remedy. Minn. Stat. § 336.2-607(3)(a). A plaintiff must also plead notice was provided. Dolan, 2021 WL 698777, at *3 (citing cases). Because Plaintiff has not alleged that he gave Defendants pre-suit notice of his breach of warranty claims, they must be dismissed.

Plaintiff concedes no pre-suit notice was provided. Accordingly, the breach of warranty claim will be dismissed.

F. New Jersey Consumer Fraud Act

Plaintiff has alleged that Defendants violated the New Jersey Consumer Fraud Act ("NJCFA") by engaging in unconscionable commercial practices, false pretense, impermissible restraint of trade and suppression, concealment and omission of material facts in connection with the promotion and sale of the Proceed Mesh with the intent that others rely on representations arising from

such conduct. (FAC ¶ 159.) Defendants argue that Minnesota law applies to each of Plaintiff's claims pursuant to Minnesota's "most significant relationship" test.

A federal court sitting in diversity applies the choice of law rules of the forum state. Highwoods Props., Inc. v. Exec. Risk Indem., Inc., 407 F.3d 917, 920 (8th Cir. 2005). Before doing so, the Court must first determine if a conflict exists between the law of two forums – in this case Minnesota and New Jersey law. Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co., 604 N.W.2d 91, 94 (Minn. 2000).

Defendants argue there is a direct conflict between Minnesota and New Jersey law as it pertains to each state's consumer fraud statutes. To prove a fraud by omission claim under Minnesota's Consumer Fraud Act ("MFCA"), Minn. Stat. § 325F.69, "a plaintiff must plead and prove not only an omission of material fact, but also special circumstances that trigger a duty to disclose." Graphic Commc'ns Local 1B Health & Welfare Fund A v. CVS Caremark Corp., 850 N.W.2d 682, 696 (Minn. 2014). "Unlike other state consumer fraud statutes, Minnesota's CFA does not make material omissions actionable." Id. Conversely, to establish an omission under the NJCFA, a "plaintiff must show that defendant

(1) knowingly concealed (2) a material fact (3) with the intention that plaintiff rely upon the concealment." Harnish v. Widener Univ. School of Law, 931 F. Supp.2d 641, 652 (D.N.J. 2013). There is no requirement to establish special circumstances that trigger a duty to disclose.

In addition, the MFCA does not provide for punitive or treble damages, Graphics Commc'ns, 850 N.W.2d at 693 (an action for violation of the MFCA brought pursuant to the Private AG Statute provides for the recovery of damages, costs and disbursements and reasonable attorney's fees), while the NJCFA authorizes treble damages. N.J. Stat. § 56:8-19 ("In any action under this section the court shall, in addition to any other appropriate legal or equitable relief, award threefold the damages sustained by any person in interest. In all actions under this section . . . the court shall also award reasonable attorneys' fees, filing fees and reasonable costs of suit.")

Because there is a conflict, the Court must next determine whether the law of both states can be constitutionally applied. Jepson v. General Cas. Co., 513 N.W.2d 467, 470 (Minn. 1994). "[F]or a State's substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or

significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." Id.

In this case, Plaintiff is a Minnesota resident, the Proceed Mesh was implanted in Plaintiff in Minnesota, and he received a substantial portion of his medical care in Minnesota. Accordingly, there are sufficient contacts to constitutionally apply Minnesota law.

The next step requires the Court to address the following factors: "(1) predictability of result; (2) maintenance of interstate and international order; (3) simplification of the judicial task; (4) advancement of the forum's governmental interest; and (5) application of the better rule of law." Jepson, 513 N.W.2d 470.

The first factor, predictability of results, applies to consensual transactions, and is therefore not relevant in a tort case. Nesladek v. Ford Motor Co., 876 F. Supp. 1061, 1068 (D. Minn. 1994). With respect to simplification of judicial task factor, Minnesota courts have held that "[a]lthough Minnesota courts are fully capable of applying the law of another state, the judicial task is 'obviously' simplified when a 'Minnesota court applies Minnesota law.'" Medtronic, Inc. v. Advanced Bionics Corp., 630 N.W.2d 438, 455 (Minn. Ct. App. 2001) (quoting Gimmestad v. Gimmestad, 451 N.W.2d 662, 666 (Minn. Ct. App. 1990)). The last

factor, better rule of law, is usually not addressed where the other factors resolve the issue. Nodak, 604 N.W.2d at 96.

The maintenance of interstate order factor is concerned with "whether the application of Minnesota law would manifest disrespect for [other state] sovereignty or impede the interstate movement of people and goods. An aspect of this concern is to maintain a coherent legal system in which the courts of different states strive to sustain, rather than subvert, each other's interests in areas where their own interest are less strong." Nodak, 604 N.W.2d at 95. "This factor is generally not implicated if the state whose law is to be applied has sufficient contacts with and interest in the facts and issues being litigated." Hughes v. Wal-Mart Stores, Inc., 250 F.3d 618, 621 (8th Cir. 2001) (citation omitted).

As set forth above, Minnesota has significant contacts with the facts relevant to this action. Plaintiff is a Minnesota resident, the Proceed Mesh was implanted in Minnesota, and he received a substantial portion of his medical care in Minnesota. Defendants are headquartered in New Jersey, but the location of headquarters alone is immaterial to the question of whether New Jersey has the most significant relationship to Plaintiff's consumer fraud claim. See Maniscalco

v. Brother Intern., Corp., 793 F.Supp.2d 696, 708 (D.N.J. 2011) aff'd 709 F.3d 202 (3d Cir. 2013).

The Court agrees that Minnesota's significant relationship test favors application of Minnesota law with regard to Plaintiff's consumer law claim. See Knox v. Samsung Elecs., Am. Inc., No. 08-cv-4308 (JLL), 2009 WL 1810728, at *4 (D.M.J. June 25, 2009) ("Although it is true that New Jersey seeks to prevent its corporations from defrauding out-of-state consumers, it is not clear to this Court that New Jersey intended out-of-state consumers to engage in end runs around local law in order to avail themselves of collective and class remedies that those states deny.") Therefore, Plaintiff's claim under the NJCFA will be dismissed. See Maniscalco, 709 F.3d at 211 (affirming district court dismissal of NJCFA claim where choice of law analysis favored California and South Carolina law).

G. Punitive Damages

Defendants assert that Plaintiff has not complied with Minn. Stat. § 549.191, which provides that a party must seek punitive damages through a motion to amend the complaint to seek such damages. Although Plaintiff filed a motion to amend his complaint, that motion did not seek to add a punitive damages claim. See one point Solutions, LLC v. Borchert, 486 F.3d 342, 348 (8th

Cir. 2007) (noting that to seek punitive damages, the motion to amend must allege the legal basis for awarding such damages and must be accompanied by one or more affidavits showing the factual basis for punitive damages). Finally, because punitive damages are derivative of his other claims, and that such claims should be dismissed, the claim for punitive damages must also be dismissed.

Plaintiff concedes he must file a motion to amend the pleadings to add allegations supporting a claim for punitive damages, therefore Plaintiff will not address punitive damages at this time.

IT IS HEREBY ORDERED that Defendants' Motion to Dismiss [Doc. No. 48] is **DENIED** in part and **GRANTED** in part as follows: The motion is denied as to Count I to the extent it asserts negligence based on design defect and failure to warn and denied as to Counts III and VI. The motion is granted in all other respects.

Date: January 3, 2022

s/Michael J. Davis
Michael J. Davis
United States District Court